



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-R-185, CMS-718-721, CMS-10123/-10124, CMS-10142, and CMS-R-262]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[OFR—INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**:

ADDRESSES: When commenting, please reference the document identifier or OMB control

number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at

<http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-R-185	Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption under State Laboratory Programs
CMS-718-721	Business Proposal Forms for Quality Improvement Organizations (QIOs)
CMS-10123/-10124	Fast Track Appeals Notices: NOMNC/DENC
CMS-10142	Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP)
CMS-R-262	Contract Year 2019 Plan Benefit Package (PBP) Software and Formulary Submission

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Extension of currently approved collection;

Title of Information Collection: Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs;

Use: The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation /licensure process is at least equal to or more stringent than those of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). If an accreditation organization is approved, the laboratories that it accredits are “deemed” to meet the CLIA requirements based on this accreditation. Similarly, if a State licensure program is determined to have requirements that are equal to or more stringent than those of CLIA, its laboratories are considered to be exempt from CLIA certification and requirements. The information collected will be used by HHS to: determine comparability/equivalency of the accreditation organization standards and policies or State licensure program standards and policies to those of the CLIA program; to ensure the continued comparability/equivalency of the standards; and to fulfill certain statutory reporting requirements. Form No.: CMS-R-185 (OMB control number: 0938-0686); Frequency: Occasionally; Affected Public: Private Sector - Business or other for-profits and Not-for-profit institutions; Number of Respondents: 12; Total Annual Responses: 96; Total Annual Hours: 384. (For policy questions regarding this collection contact Arlene Lopez at 410-786-6782.)

2. Type of Information Collection Request: Revision of a currently approved collection;

Title of Information Collection: Business Proposal Forms for Quality Improvement

Organizations (QIOs); Use: The submission of proposal information by current quality improvement associations (QIOs) and other bidders, on the appropriate forms, will satisfy our

need for meaningful, consistent, and verifiable data with which to evaluate contract proposals. We use the data collected on the forms associated with this information collection request to negotiate QIO contracts. We will be able to compare the costs reported by the QIOs on the cost reports to the proposed costs noted on the business proposal forms. Subsequent contract and modification negotiations will be based on historic cost data. The business proposal forms will be one element of the historical cost data from which we can analyze future proposed costs. In addition, the business proposal format will standardize the cost proposing and pricing process among all QIOs. With well-defined cost centers and line items, proposals can be compared among QIOs for reasonableness and appropriateness. Form Number: CMS-718-721 (OMB control number: 0938-0579); Frequency: Annually; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 20; Total Annual Responses: 20; Total Annual Hours: 1,000. (For policy questions regarding this collection contact Benjamin Bernstein at 410-786-6570.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Fast Track Appeals Notices: NOMNC/DENC; Use: Providers shall deliver a Notice of Medicare (Provider) Non-Coverage (NOMNC) to beneficiaries, enrollees, or both beneficiaries and enrollees no later than two days prior to the end of Medicare-covered services in skilled nursing facilities, home health agencies, comprehensive outpatient rehabilitation facilities, and hospices. Beneficiaries, enrollees or both beneficiaries and enrollees will use this information to determine whether they want to appeal the service termination to their Quality Improvement Organization (QIO). If the beneficiaries, enrollees or both beneficiaries decide to appeal, the Medicare provider or health plan will send the QIO and

appellant a Detailed Explanation of Non-Coverage (DENC) detailing the rationale for the termination decision. Form Number: CMS-10123 and CMS-10124 (OMB control number: 0938-0953); Frequency: Occasionally; Affected Public: Private sector - Business or other for-profits and Not-for-profit institutions; Number of Respondents: 28,177; Total Annual Responses: 6,017,832; Total Annual Hours: 1,111,196. (For policy questions regarding this collection contact Janet Miller at 404-562-1799.)

4. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); Use: We require that Medicare Advantage organizations and Prescription Drug Plans complete the BPT as part of the annual bidding process. During this process, organizations prepare their proposed actuarial bid pricing for the upcoming contract year and submit them to us for review and approval. The purpose of the BPT is to collect the actuarial pricing information for each plan. The BPT calculates the plan's bid, enrollee premiums, and payment rates. We publish beneficiary premium information using a variety of formats (www.medicare.gov, the Medicare & You handbook, Summary of Benefits marketing information) for the purpose of beneficiary education and enrollment. Form Number: CMS-10142 (OMB control number: 0938-0944); Frequency: Yearly; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 555; Total Annual Responses: 4,995; Total Annual Hours: 149,850. (For policy questions regarding this collection contact Rachel Shevland at 410-786-3026.)

5. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Contract Year 2019 Plan Benefit Package (PBP) Software and

Formulary Submission; Use: We require that Medicare Advantage and Prescription Drug Plan organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to us for review and approval. We publish beneficiary education information using a variety of formats. The specific education initiatives that utilize PBP and formulary data include web application tools on www.medicare.gov and the plan benefit insert in the Medicare & You handbook. In addition, organizations utilize the PBP data to generate their Summary of Benefits marketing information. Form Number: CMS-R-262 (OMB control number 0938-0763); Frequency: Yearly; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 520; Total Annual Responses: 5,675; Total Annual Hours: 54,550. (For policy questions regarding this collection contact Kristy Holtje at 410-786-2209.)

Dated: September 19, 2017. _____

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

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